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Clinical Trials Results Indicate New Ways to Use Drugs To Treat Breast Cancer

The results from several clinical trials, presented at the American Society of Clinical Oncology (ASCO) annual meeting in New Orleans last week highlight research progress that spans the continuum of breast cancer—from prevention to reducing the risk of recurrence to treating advanced disease. The trials included exploring new hormonal therapies that may reduce cancer risk, developing alternatives to tamoxifen in the adjuvant setting, and optimizing chemotherapy dosing schedules.

One of the most significant findings

pertains to decreasing the dosing interval for the chemotherapeutic agent, paclitaxel (Taxol), for women with metastatic breast cancer. The trial, conducted by the Cancer and Leukemia Group B (CALGB), a Cooperative Group funded by the National Cancer Institute (NCI), examined the effects of weekly administration of paclitaxel versus the standard 3-week schedule on tumor response and delay of disease progression.

Forty percent of patients who received
(continued on page 2)

Director's Update

Charting Our Progress: Targeted Therapies Coming into Their Own

The words "targeted therapy" were on everybody's lips last week at the 40th annual ASCO meeting. And with good reason. Encouraging results were reported in a number of clinical trials, proving that we are making progress in our efforts to attack cancer at its most fundamental levels.

In one phase III trial, for example, use of the investigational agent erlotinib (Tarceva)—which, like the recently FDA-approved gefitinib (Iressa), targets the

epidermal growth factor receptor—improved survival in patients with advanced lung cancer. In another phase III trial, bortezomib (Velcade), which inhibits the proteasome pathway and affects both cancer cell proliferation and stability, significantly improved 1-year survival in multiple myeloma patients who had relapsed or become resistant to standard therapies. And several earlier stage trials involving the
(continued on page 2)

Some of the Targeted Drugs Recently Approved by the FDA

Agent	Target	FDA Approval/Indication for Use
Bevacizumab (Avastin)	VEGF	Approved Feb. 2004 for advanced metastatic colorectal cancer
Cetuximab (Erbixux)	EGFR	Approved Feb. 2004 for advanced metastatic colorectal cancer
Tositumomab (Bexxar)	CD20	Approved June 2003 for relapsed non-Hodgkin's lymphoma
Gefitinib (Iressa)	EGFR	Approved May 2003 for advanced lung cancer

(Clinical Trials continued from page 1)

paclitaxel weekly responded to treatment compared with 28 percent of patients on the standard regimen. Disease progression was 9 months with weekly chemotherapy versus 5 months with standard chemotherapy.

“The weekly schedule is well tolerated and appears more effective in the metastatic setting. This result parallels a previous CALGB study reported last year that also reduced the dosing interval for paclitaxel in combination with other drugs and showed a beneficial effect,” said Dr. Jeffrey Abrams, acting chief of the Clinical Investigations Branch at NCI’s Cancer Therapy Evaluation Program.

Other results presented at the meeting included updated findings from an international clinical trial of the drug letrozole (Femara) in reducing the risk of recurrent breast cancer after 5 years of tamoxifen therapy. Initial results of the trial, led by the National Cancer Institute of Canada, demonstrated that letrozole significantly reduced the risk of recurrence when taken after 5 years of tamoxifen therapy.

New data, with a median follow-up of 2.5 years, demonstrated that letrozole reduced metastasis by 40 percent compared with placebo in both node-negative and node-positive patients. There was also a 39-percent increase in overall survival for node-positive patients taking letrozole. “Of equal interest to the good news on survival,” said Dr. Abrams, “was that additional follow-up did not show any further increase in side effects related to bone fractures or the heart.”

Encouraging results were also seen in prevention. The Continuing Outcomes Relevant to Evista (CORE) study allowed women with osteoporosis, who had been initially randomized to raloxifene (Evista) or placebo for 4 years, to undergo a second randomization to

raloxifene or placebo for an additional 4 years. Women taking raloxifene had a 59 percent lower risk of breast cancer after 4 years on the follow-up trial compared with those taking the placebo. Similar to results reported from the Tamoxifen Prevention Trial, the incidence of ER-positive breast cancer was reduced by 66 percent but there was no reduction in ER-negative cancers.

Researchers cautioned that these results may be limited because the study included only postmenopausal women with osteoporosis; it is not clear if the results will hold true for other women.

It is premature to recommend that postmenopausal women take raloxifene outside of a clinical trial to reduce their risk of breast cancer, according to Dr. Silvana Martino, the principal investigator of the CORE study. She noted that two large trials with raloxifene are underway, including the STAR trial, which is comparing raloxifene with tamoxifen in the prevention of breast cancer. ♦

(Director’s Update continued from page 1)
investigational anti-angiogenesis drugs SU11248 and BAY 43-9006, both of which are multitargeted agents, also demonstrated promise in treating metastatic renal cell carcinoma.

Other studies shed light on additional avenues of treatment, such as combining new therapies. One intriguing combination therapy that had positive results in metastatic renal cell carcinoma was the use of erlotinib and the vascular endothelial growth factor inhibitor bevacizumab (Avastin), which was recently approved by the FDA.

Studies presented at ASCO also showed that we are learning to use existing therapies more effectively. As you may have read in last week’s *Bulletin*, for instance, adjuvant chemotherapy after surgery for lung cancer had striking results, effectively creating a new standard of care for patients with advanced lung cancer. Or, as reported

in this issue, in a study of patients with metastatic breast cancer, weekly administration of paclitaxel proved superior to the more conventional approach of administration every 3 weeks.

Of course, not all of the data presented at this year’s meeting were positive; nor should we expect them to be. We are engaged in a difficult scientific pursuit to outwit and outmaneuver a stealthy and adaptable foe that has shown an uncanny ability to return after we thought and hoped it was long gone.

More important, though, the results from this year’s ASCO meeting demonstrate that we are on the right course. Discussions of “targeted therapies” in years past were often shrouded in tones of uncertainty. Just a few years later, these therapies represent a major theme of perhaps the most important clinical oncology meeting in the world. Meanwhile, we are using advances in areas like genomics to learn how we might use these therapies more effectively. Several recent studies have found, for example, genetic mutations that were predictive of a positive response to targeted therapies, while others have discovered “genetic signatures” that may help predict response to treatment.

The excitement was palpable among the presenters and their audiences during the ASCO presentations. There was cautious optimism that we are moving closer to providing better, less toxic treatments that will aid in curing some cancers while allowing us to manage others like a chronic disease.

Yes, at times there has been uncertainty. At other times, there have been hopeful discussions about the day when we might be able to apply advances like those presented at ASCO in the everyday treatment of our patients. And now, we are on the brink of translating that hope into reality. ♦

*Dr. Andrew C. von Eschenbach
Director, National Cancer Institute*



Cancer Research Highlights

High Fracture Risk for Prostate Cancer Patients on Androgen-Deprivation Therapy

Patients with nonmetastatic prostate cancer on androgen-deprivation therapy with drugs known as GnRH agonists are at significantly increased risk for fractures, researchers reported last week at the ASCO annual meeting in New Orleans. GnRH agonists are broadly used in prostate cancer to reduce testosterone that may fuel tumor growth and to help reduce pain, explained the study's lead author, Dr. Matthew R. Smith of Massachusetts General Hospital in Boston. Although it is known that these drugs affect bone density, data on the risk of adverse effects, such as fractures, linked to their use have been limited.

Dr. Smith and his colleagues looked at a random sample of more than 11,000 Medicare beneficiaries with nonmetastatic prostate cancer and compared the fracture risk between those who had and had not received GnRH agonists. The overall risk of developing any clinical fracture associated with a GnRH agonist was 25 percent, Dr. Smith said. More specifically, use of GnRH agonists increased the risk of hip fracture by 46 percent and vertebral fracture by 63 percent. Longer duration of GnRH use was associated with increased fracture risk, he added.

"For men who require androgen-deprivation therapy, screening for osteoporosis and interventions to prevent fractures should become the standard of care," Dr. Smith advised.

"However, no studies have been done to determine how to prevent or reduce the risk of fractures in this patient population," he added. One potential option, he said, are bisphosphonates, which have been shown to increase bone mineral density in those patients who were given GnRH agonists.

Chemo Plus Radiation Improves Survival in Often-Fatal Brain Cancer

Researchers have shown for the first time in a large study that adding a chemotherapy drug to radiation for the treatment of glioblastoma multiforme (GBM)—a common, aggressive, and highly fatal form of brain cancer—can improve survival. In the phase III international trial, 26 percent of patients with GBM treated with the chemotherapy drug temozolomide (Temodar) and radiation therapy were likely to live for 2 years after treatment, compared with 10 percent of patients treated with radiation therapy alone.

The study results, presented at the ASCO annual meeting, included 573 patients with GBM who were randomly assigned to receive the current standard therapy: surgery followed by radiation, or temozolomide daily, beginning at the same time as radiation therapy and continuing for 6 weeks following radiation. The median survival in the radiation-plus-temozolomide group was 14.6 months compared with 12.1 months in the radiation-alone group. Progression-free survival was 7.2 months in the temozolomide group and 5 months in the other group.

"Our data clearly establish a new treatment standard for GBM," said the study's lead author, Dr. Roger Stupp, of the University Hospital Multidisciplinary Oncology Center in Lausanne, Switzerland. The trial was conducted by the European Organization for Research and Treatment of Cancer and the National Cancer Institute of Canada Clinical Trials Group. Based on promising early studies of the drug, "most U.S. oncologists have been treating patients with GBM with radiation followed by temozolomide," commented Dr. Howard Fine of the NCI Center for Cancer Research (CCR). He agreed that this treatment has now shown to be effective as a first-line treatment, but added that "we have a long way to go" in developing clearly superior treatments for GBM patients.

Studies Show Survival Improvement in Advanced Prostate Cancer

Results from two similar phase III clinical trials, presented at the ASCO annual meeting, offered some hope to men with advanced, metastatic prostate cancer that has become resistant to standard hormone therapy. Both studies tested chemotherapy treatment regimens using the drug docetaxel (Taxotere) against the accepted standard of care for such patients, the two-drug regimen mitoxantrone and prednisone. The current standard has significantly limited effectiveness, with a median survival after treatment initiation of 10 to 12 months.

The first trial, led by Dr. Mario Eisenberger of Johns Hopkins School of Medicine, compared three treatment regimens: the use of prednisone and docetaxel weekly or once every 3 weeks against the standard treatment. With a median follow-up of approximately 21 months, the docetaxel regimens provided a 24 percent survival *(continued on page 4)*

(Research Highlights continued from page 3) improvement (18.9 months) compared with the standard treatment (16.4 months). Patients on docetaxel regimens were also more likely to see significant reductions in PSA levels and were less likely to experience significant bouts of pain.

The second trial, led by the Southwest Oncology Group, compared the use of docetaxel and estramustine with standard treatment in men with advanced, hormone-refractory prostate cancer. According to the trial's principal investigator Dr. Daniel P. Petrylak, median survival was 18 months for patients treated with the docetaxel/estramustine regimen versus 16 months for those treated with the standard therapy, an approximately 20 percent reduction in risk of death. In both studies, the incidence of severe side effects was worse in the patients treated with docetaxel.

During a news conference, the researchers were asked whether a 2-month improvement in survival could really be considered significant. "These are people with incurable disease," responded Dr. Robert J. Mayer, from the Dana-Farber Cancer Institute, who moderated the news conference. "Multiple earlier trials have not shown that they could move the [survival] curve. The fact that two separate studies conducted at nearly the same time showed a survival improvement gives us something to build upon."

Expression Profile Changes Show Erlotinib May Have Additional Targets in Breast Cancer

New data presented at the ASCO annual meeting suggests that erlotinib (Tarceva), an investigational therapeutic agent that targets the epidermal growth factor receptor (EGFR)—which plays an important

role in cancer cell proliferation—may have additional cellular targets. Previous research led by Dr. Sandra Swain of NCI's CCR using breast tumor biopsies had shown no clinical response and no proliferation changes in tumors after treatment with erlotinib. However, in one EGFR-positive tumor, expression of the EGFR protein decreased after treatment.

To conduct the new study, a team led by Drs. Swain and Xiaowei Yang, also from CCR, measured RNA expression profiles for 10 paired pre- and post-treatment breast tumor samples from patients with metastatic breast cancer. Only one tumor pair was shown to be EGFR-positive, and in that tumor the RNA levels of EGFR remained unchanged upon treatment with erlotinib. The drug did, however, alter the expression levels of 26 genes, independent of whether the tumors were EGFR-positive or EGFR-negative. These included genes that encode extracellular matrix components, proteases, signal transduction proteins, transcription factors, oncogenes/tumor suppressors, and enzymes involved in drug metabolism.

The researchers hypothesize that the reduction in EGFR protein but not RNA upon treatment in the EGFR-positive tumor may be due to accelerated degradation of the receptor. They also suggest that the fact that changes in gene expression occurred in these tumors regardless of EGFR expression status indicates that erlotinib may affect multiple targets or pathways. "This finding could provide physicians with additional information to understand drug effects in patients," said Dr. Swain. "We are in the process of analyzing the targets identified and collaborating with the U.S. Food and Drug Administration (FDA) to further study other signaling kinases that could be affected by erlotinib."

Researchers Develop "Knock-In" Mouse Model of Plasma Cell Cancers

After manipulating genes involved in cell growth and cell death (apoptosis), researchers from the Laboratory of Genetics in NCI's CCR have developed an improved mouse model of plasma cell neoplasms. The study results, published in the June 15 *Journal of Clinical Investigation*, offer new possibilities for understanding what causes these cancers, as well as how to prevent and treat them.

In this study, researchers focused on two genes: *Myc* and *Bcl-X_L*. *Myc* is involved in cell growth and proliferation, and *Bcl-X_L* suppresses apoptosis. Deregulated expression of these genes has already been linked with plasma cell neoplasms in both humans and mice, but the mechanism of neoplastic development is not understood. Researchers inserted constitutively expressed versions of these genes into the mouse genome according to each of the three possible permutations: *Myc* transgenic or "knock-in" mice; *Bcl-X_L* transgenic mice; and double transgenic *Myc/Bcl-X_L* mice.

The study showed that after 380 days, less than 10 percent of mice carrying the *Myc* transgene developed B-cell tumors and all mice with the *Bcl-X_L* mutation remained tumor free. All of the *Myc/Bcl-X_L* transgenic mice, however, developed plasma cell tumors within 135 days. The resulting tumors produced monoclonal Ig, infiltrated the bone marrow, and produced large amounts of *Myc* and *Bcl-X_L* protein—features similar to the multiple myeloma seen in humans.

"This information, and other insights gleaned from *Myc/Bcl-X_L* mice, may lead to new interventions to inhibit the *Myc/Bcl-X_L* collaboration for the benefit of the human plasma cell neoplasm patient," the authors concluded. ♦

NCI and CMS to Collaborate to Improve Patient Access to Treatment

NCI and the Centers for Medicare & Medicaid Services (CMS) have announced that they are collaborating to improve the process for bringing new lifesaving cancer treatments to patients. Implicit in this collaboration will be increased information that clinicians and patients can use to guide decisions on directing new technologies to improve the quality and outcome of life with cancer.

“We have collaborated with CMS in the past,” said NCI Director Dr. Andrew C. von Eschenbach, “but we expect this unique and important partnership to produce results that will make a significant impact on the way we deliver evidence-based care to cancer patients.

To this end, NCI and CMS are developing a joint Memorandum of Understanding with five areas of collaboration:

- Identification of high-priority clinical questions on the optimal use of new technologies and the creation of postapproval processes to study them
- Definition of a consultation process between NCI and CMS experts for evaluating new diagnostics and technologies for payment and coverage decision making
- Development of more efficient methods for collecting clinical evidence on technologies and strategies and ways of making them more available to patients, clinicians, and researchers, including the addition of CMS claims data on the NCI bioinformatics grid, caBIG

- Development of a joint process for the prospective identification and evaluation of emerging technologies so that reimbursement policies will fully anticipate them and expedite their adoption in the marketplace
- Identification of opportunities for sharing data and resources to address issues such as disparity in cancer care, unwarranted variations in treatment, and palliative and end-of-life care.

“We need to work together to serve society’s long-term need for new knowledge, new technologies, and, above all, effective health care that is affordable for all,” said CMS Administrator Dr. Mark B. McClellan.

The two agencies will develop a strategic approach for prioritizing clinical questions identified by clinicians and patients as lacking the information necessary for guiding their decision making between competing or new therapies. Since these therapies must first be approved by the FDA, the NCI-CMS partnership will also build upon successful NCI-FDA collaborations to better align all three agencies’ efforts.

Recognizing that changes in the understanding of the biology of cancer are leading to a shift in diagnostic and therapeutic approaches, NCI and CMS will work together to ensure that the reimbursement infrastructure can adapt to potentially critical changes. Their alignment will ensure earlier access to safe and effective new technologies for patients. ♦

Funding Opportunities

Rapid Access to Intervention Development (RAID)

NOT-CA-04-019

Application Receipt Date: Aug. 1, 2004

NCI is requesting applications for the Rapid Access to Intervention Development (RAID) initiative. RAID will make available to academic investigators, on a competitive basis, the preclinical development contract resources of NCI’s Developmental Therapeutics Program (DTP). The goal of RAID is the rapid movement of novel molecules and concepts from the laboratory to the clinic for proof-of-principle clinical trials. Possible tasks may include production, bulk supply, goods manufacturing, process manufacturing, formulation, and toxicology. Suitable agents for RAID will include small molecules, biologics, or vaccines.

For more information see http://crici.nci.nih.gov/4abst.cfm?initiativeparfa_id=2123

Inquiries: RAID, Office of Associate Director, raid@dtpax2.ncicrf.gov

Midcareer Investigator Award in Patient-Oriented Research (K24)

PA-04-107

Application Receipt Date: Oct. 1, 2004; Feb. 1, 2005; June 1, 2005; Oct. 1, 2005; Feb. 1, 2006; June 1, 2006; Oct. 1, 2006; Feb. 1, 2007

This award will provide support for clinician investigators to allow them protected time to devote to patient-oriented research (POR) and to act as research mentors primarily for clinical residents, clinical fellows, and/or junior clinical faculty. This award is *(continued on page 6)*

(Funding Opportunities continued from page 5)
primarily intended for clinician investigators who are at the Associate Professor level or are functioning at that rank in an academic or equivalent nonacademic setting, and who have an established record of independent, peer-reviewed Federal or private research grant funding in POR.

The PA will use the K24 award mechanism.

For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=2120

Inquiries: Dr. Lester Gorelic,
lg2h@nih.gov

Cross-Disciplinary Translational Research at NIH

PA-04-109

Application Receipt Dates: Oct. 1, 2004; Feb. 1, 2005; June 1, 2005; Oct. 1, 2005; Feb. 1, 2006; June 1, 2006; Oct. 1, 2006; Feb. 1, 2007; June 1, 2007

NCI joins the National Institute on Drug Abuse to invite applications for research that will have a practical impact on the treatment and prevention of drug abuse through the development of new research technologies that are based on existing basic and/or clinical research knowledge and technology transfer knowledge. This PA is intended to encourage projects that provide tools and resources that serve as platforms for the development of effective prevention and treatment strategies.

This PA will use the NIH research project grant (R01), small grant (R03), and exploratory/developmental (R21) award mechanisms.

For more information see http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=2122

Inquiries: Dr. Jacqueline Stoddard,
stoddaja@mail.nih.gov ♦



Featured Clinical Trial

Chemoprevention of Recurrent Bladder Cancer

Name of the Trial

Phase IIB/III Randomized Chemoprevention Study of Celecoxib in Patients with Superficial Transitional Cell Carcinoma of the Bladder at High Risk for Recurrence (MDA-ID-99368). See the protocol summary at <http://cancer.gov/clinicaltrials/MDA-ID-99368>.

Principal Investigator

Dr. Anita L. Sabichi of the University of Texas M.D. Anderson Cancer Center

Why Is This Trial Important?

Most patients with newly diagnosed bladder cancer have superficial bladder tumors (i.e., tumors that have not spread beyond the lining of the bladder). Patients with superficial bladder cancer can often be cured by surgery. However, the risk of the cancer returning following potentially curative surgery is high.

Celecoxib (Celebrex), a COX-2 selective nonsteroidal anti-inflammatory drug (NSAID), has shown promise in animal studies for the prevention of many cancers (e.g., bladder, colorectal, esophageal, skin, breast, and prostate). It has also been proven to reduce colorectal polyps in patients with familial adenomatous polyposis, a condition that leads to the development of colorectal cancer. This trial will study the effectiveness of celecoxib in preventing the recurrence of superficial bladder cancer, which is characterized by high levels of the COX-2 enzyme.

“NSAIDs are arguably the most promising chemopreventive agents for epithelial cancers, such as bladder cancer,” said Dr. Jaye Viner of the NCI Division of Cancer Prevention. “With this trial, we are exploring the possible benefits of celecoxib in bladder cancer patients who are at high risk for recurrence.

“Superficial bladder cancer often recurs, even after potentially curative surgery and standard follow-up treatment. There is a strong need to develop safe and effective interventions to reduce this risk,” added Dr. Viner.

Who Can Join This Trial?

Researchers seek to enroll 152 patients aged 18 and over with superficial transitional cell carcinoma of the bladder. See the full list of eligibility criteria for this trial at <http://cancer.gov/clinicaltrials/MDA-ID-99368>.

Where Is This Trial Taking Place?

The University of Texas M.D. Anderson Cancer Center is coordinating this trial. Multiple study sites in the United States are recruiting patients to participate. A complete list of study sites is available from study investigators listed at <http://cancer.gov/clinicaltrials/MDA-ID-99368>.

Who to Contact

See the list of study contacts at <http://cancer.gov/clinicaltrials/MDA-ID-99368> or call the NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). The call is toll free and completely confidential. ♦

An archive of “Featured Clinical Trial” columns is available at <http://cancer.gov/clinicaltrials/ft-all-featured-trials>.

Notes

NCI Receives Communications Awards

NCI and its contractor, Matthews Media Group, Inc. (MMG), were honored with several Blue Pencil Awards from the National Association of Government Communicators (NAGC). NCI and MMG received two first-place awards and three awards of excellence for NCI's publications. First-place awards went to the brochure, "A Guide to Cancer Clinical Studies" and its press kit, "Cancer of the Month." Awards of excellence went to the book, *Making Health Communication Programs Work: A Planner's Guide* (also known to many as "The Pink Book"); to the display, "CSSC African American and Hispanic Banner Display;" and to the video news release, "Prostate Cancer Prevention Trial."

The NAGC is a network of federal, state, and local government employees who disseminate information within and outside government. Its Blue Pencil and Gold Screen Awards recognize excellence in written, filmed, audio/videotaped, published, and photographed government information products.

DCEG Scientists Receive Departmental Service Awards

Drs. Shelia Zahm and Robert Hoover



are recipients of the 2004 Department of Health and Human Services Secretary's Award

for Distinguished Service, which will be presented by Secretary Thompson on July 14. The award recognizes individuals for outstanding abilities, leadership skills, and exceptional contributions to the mission of the department.

Dr. Zahm, deputy director of the Division of Cancer Epidemiology and Genetics (DCEG), was cited for her leadership and coordination of national research programs in environmental and occupational cancers. She has played a key role in sustaining and strengthening a collaborative program of epidemiologic and interdisciplinary research into the environmental and genetic determinants of cancer.

Dr. Hoover, director of DCEG's Epidemiology and Biostatistics Program, was cited for research in identifying environmental and genetic determinants of cancer, as well as his contributions to epidemiology and public health. Dr. Hoover conducted the first study linking hormone replacement therapy to breast cancer.

IOM Releases Breast Cancer Screening Report

The Institute of Medicine (IOM) of the National Academies last week released "Saving Women's Lives: Strategies for Improving the Early Detection and Diagnosis of Breast Cancer." In this new report, an IOM committee concludes that access to breast cancer screening by American women is decreasing because fewer radiologists are entering the field and the number of mammography facilities is decreasing. In 2003, for instance, there were 8,600 mammography facilities operating in the United States, compared with 9,400 in 2000.

Training nonphysician health care professionals to prescreen or double-read mammograms may help expand facilities' capacity, while providing the same accuracy as radiologists, IOM suggests. Practices that help other countries to have lower rates of false-positive results than the United States

should also be instituted here, the report recommends.

Though new methods of breast cancer detection are being evaluated, "improving and increasing the use of current mammography technology is the most effective strategy we have right now for further reducing the toll of breast cancer," said Dr. Edward Penhoet, chair of the IOM committee.

The full report can be found at <http://books.nap.edu/catalog/11016.html>.

Science Writer Seminar Rescheduled

The Science Writer Seminar originally scheduled for June 11 will take place on Friday, June 18 at from 10:00 a.m.–1:00 p.m., at the IOM, Keck Center of the National Academies, 500 Fifth Street, N.W., Room #201, Washington, D.C. This seminar, sponsored by NCI and IOM, will offer insights and details beyond the scope of the IOM Report on breast cancer screening, particularly as they relate to techniques and technologies beyond mammography. ♦

CCR Grand Rounds

June 22: Dr. Ronald D.G. McKay of the Laboratory of Molecular Biology, National Institute of Neurological Disorders and Stroke, will present "The Importance of Embryonic Stem Cells in Science and Medicine."

June 29: Dr. James C. Yang of NCI's Center for Cancer Research will present "Biological Approaches to the Treatment of Metastatic Renal Cancer."

CCR Grand Rounds are held 8:30 to 9:30 a.m. at the NIH campus in Bethesda, Md. in the Clinical Center's Lipsett Amphitheater. ♦

Beyond Bench to Bedside: Fulfilling the Promise of Today's Research Advances

Last week in New Orleans, the American Society of Clinical Oncology (ASCO) celebrated 40 years of quality cancer care, but more than ever before, ASCO participants from across the country and around the world stressed the need for a balanced research agenda that contemplates the ultimate goal of reaching the public with innovative prevention and treatment strategies that are evidence-based, cost-effective, accessible, and affordable. ASCO recognizes that quality care cannot be achieved if research does not reach the bedside and that oncologists in the community are the effector arm to translate cancer research into practical applications.

It is clear that the promise of discovery created by new and targeted therapies from the fields of genomics and proteomics has the possibility to achieve cancer interventions never before possible. It is equally evident that the improvements in health status to be generated from our greater understandings of the molecular biology of cancer, the

mechanisms and toxicities of drugs, biologicals, and other treatments, will not be fully realized if we, as a community, do not also contemplate the long-term effects—physiological, psychosocial, economic, and cultural—that current and developing treatments will have on patients, survivors, providers, and their communities. Delivery of quality cancer care will not be achieved if research generates solutions that are innovative but not affordable.

NCI Director Dr. Andrew C. von Eschenbach reiterated the NCI 2015 goal “to eliminate the suffering and death due to cancer,” with a renewed enthusiasm, strengthened by the commitment of the ASCO leadership, the U.S. Food and Drug

Administration (FDA) and more recently the Centers for Medicaid and Medicare Services (CMS) to collaborate on a joint research agenda. This collaboration begins

with a common language and is supported by a shared infrastructure to allow research results to be compared quickly, providing a platform to create opportunities for CMS and FDA to participate in the design of effective clinical trials involving industry, govern-

ment, academia, and the general medical public. Importantly, these collaborations will offer the opportunity to evaluate clinical outcomes with a view to delivering affordable cancer care to all. The commitment is clear. It is now incumbent on all of us to carry this vision through to fruition. ♦



*Dr. LaSalle D. Leffall, Jr.
Chairman
President's Cancer Panel*

This *NCI Cancer Bulletin* is produced by the National Cancer Institute (NCI). NCI, which was established in 1937, leads a national effort to eliminate the suffering and death due to cancer. Through basic and clinical biomedical research and training, NCI conducts and supports research that will lead to a future in which we can prevent cancer before it starts, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.

For more information on cancer, call 1-800-4-CANCER or visit <http://cancer.gov>.

NCI Cancer Bulletin staff can be reached at ncicancerbulletin@mail.nih.gov.

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